FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

113–130

COSMETICS

The cases reported herewith were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *April 18, 1946.*

CONTENTS

COSMETICS ACTIONABLE BECAUSE OF ADULTERATION WITH POISONOUS OR DELETERIOUS SUBSTANCES

113. Adulteration of Nu-Charme Perfected Brow Tint. U. S. v. 26 Cartons of Nu-Charme Perfected Brow Tint (and 1 seizure action against another lot of the same product). Motion to dismiss denied. Judgment of district court ordering product condemned and destroyed appealed to circuit court of appeals. Judgment of district court affirmed. (F. D. C. Nos. 12833, 13790. Sample Nos. 61272–F., 61335–F.)

LIBELS FILED: July 6 and September 16, 1944, Western District of Louisiana; amended January 16, 1945.

ALLEGED SHIPMENT: Between the approximate dates of April 14 and May 5, 1944, by James B. Byrd, trading as the Nu-Charme Laboratories, Texarkana, Ark.-Tex.

PRODUCT: 26 cartons and 3 7/12 dozen packages, each containing, among other items, 4 bottles of solutions labeled "Nu-Charme No. 1," "Nu-Charme No. 2," "Nu-Charme No. 4," and "Nu-Charme No. 5," and a package of powder labeled "Nu-Charme No. 3," at Shreveport, La.

Examination showed that Nu-Charme No. 1 consisted essentially of 4 percent paraphenylenediamine dissolved in water; that Nu-Charme No. 2 was a solution of hydrogen peroxide; that Nu-Charme No. 3 consisted of magnesium oxide; that Nu-Charme No. 4 was a solution of boric acid; and that Nu-Charme No. 5 was light mineral oil.

LABEL, IN PART: "Nu-Charme Perfected Brow Tint Jet Black."

NATURE OF CHARGE: Adulteration, Section 601 (a), the product contained a poisonous or deleterious substance, paraphenylenediamine, which might have rendered it injurious to users under the conditions of use prescribed in the labeling; and, Section 601 (e), the product was not a hair dye and it bore and contained a coal-tar color that has not been listed for use in cosmetics in accordance with the regulations and is other than one from a batch that has been certified.

DISPOSITION: March 17, 1945. The cases having been consolidated for trial, James B. Byrd, trading as the Nu-Charme Laboratories, appeared as claimant and filed a motion to dismiss the libel. Further proceedings are set forth in detail in the following opinions of the district court:

DAWKINS, *District Judge:*

[*Opinion delivered March 16, 1945.*]

"These two cases involve the same issues and will be disposed of in one opinion, in which the Government seeks to condemn and have destroyed certain quantities of the product known as 'Nu-Charme Perfected Brow Tint * * *,' found on analysis to consist essentially of para-phenylenediamine, approximately four per cent, dissolved in water * * * and that the article is adulterated within the meaning of T. 21 USCA 361 (a), in that it contains a poisonous and deleterious substance, namely, para-phenylenediamine, which may render it injurious under the conditions prescribed in the labelling thereof, as follows:

* * * Use Glass, China or Wooden Dish for Mixing Fifteen (15) drops Solution No. 1 with Fifteen (15) drops Solution No. 2; to this add enough Powder No. 3 to make thick paste. Be sure paste will not run. Application Using small clean orange stick apply dye mixture to lashes * * * then to brows. Leave mixture on until dry * * * 10 to 15 minutes. * * * Do Not Let Patron Open Eyes Until All of Mixture Has Been Removed. * * *

"The seizure was made and appropriate proceedings taken for the condemnation as having been sold in interstate commerce. Thereupon, James B. Bird, doing business as Nu-Charme Laboratories, intervened and claimed ownership of the seized product. Among other things he admitted that it was a cosmetic within the intent and meaning of the Act of June 25th, 1938, known as the 'Pure Food, Drug and Cosmetic Act'; but denied that it was adulterated within the meaning of T. 21 USCA 361 (a) or that it contained poisonous and deleterious substances, which render it injurious to users under conditions of use prescribed in the label thereof. Claimant then quoted in detail the directions for preparation and use which he alleged accompanied the product.

"On January 16, 1945, plaintiff filed an amended libel in which it was alleged as follows:

That the article heretofore herein seized is further adulterated within the meaning of 21 U.S.C. 361 (e), in that it is not a hair dye and bears and contains a coal tar color that has not been listed for use in cosmetics in accordance with regulations of the Administrator of the Federal Security Agency pursuant to 21 U. S. C. 364, and is other than one from a batch that has been certified.

"On February 19, 1945, the following proceedings were also filed: (1) a second amendment to the libel, from which the following is quoted:

'Notwithstanding, in order to have the pertinent regulations before the Court, libelant shows that the Federal Register of Tuesday, May 9, 1939, Volume 4, Number 89, beginning on page 1922, contains the following:

RULES, REGULATIONS, ORDERS

TITLE 21—FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

IN THE MATTER OF PUBLIC HEARING FOR PURPOSE OF RECEIVING EVIDENCE UPON THE BASIS OF WHICH REGULATIONS MAY BE PROMULGATED FOR LISTING OF COAL-TAR COLORS WHICH ARE HARMLESS AND SUITABLE FOR USE IN FOODS, DRUGS, AND COSMETICS, DRUGS AND COSMETICS, AND EXTERNALLY APPLIED DRUGS AND COSMETICS: FOR CERTIFICATION OF BATCHES OF SUCH COLORS: FOR PROCEDURES THEREUNDER: AND FOR PAYMENT OF FEES THEREFOR.

ORDER OF THE SECRETARY PROMULGATING REGULATIONS EFFECTIVE ON PUBLICATION

Pursuant to, and under and by virtue of, the authority and direction of the Federal Food, Drug and Cosmetic Act (Sec. 701, 52 Stat. 1055; 21 U. S. C. 371 (e); Sec. 406 (b), 52 Stat. 1049; 21 U. S. C. 346 (b) Sec. 504, 52 Stat. 1052; 21 U. S. C. 354; Sec. 604, 52 Stat. 1055; 21 U. S. C. 364; Sec. 706, 52 Stat. 1058; 21 U. S. C. 376), and based upon substantial evidence of record at the hearing in the above-entitled matter detailed findings of fact are made, as follows:

FINDINGS OF FACT

Coal-tar colors—Derivation—scope of term.

That coal-tar colors are materials consisting of one or more substances which either are made from coal-tar, or are capable of derivation from intermediates of the same identity as coal-tar intermediates. They include all substances from these sources which are themselves colored and impart their color to the substance to which they are applied, and they also include those compounds which do not themselves possess the color imparted to the substance to which they are applied but which when applied to such substance, impart color. (For example: Orange I is prepared from coal-tar intermediates. It is itself colored and imparts color when applied to a substance. Alizarin may be made either from coal-tar intermediates or from the root of the madder plant. It is colored and imparts color and is considered a coal-tar color whether derived from coal-tar or from a natural source. Paraphenylenediamine is colorless but is considered a coal-tar color, since it is derived from coal-tar and imparts color when applied to other substances.) Coal-tar colors may also include diluents or substrata. In the manufacture of coal-tar colors all impurities are not completely eliminated.

2.

Definitions of terms used in regulations. (Unnecessary here)

* * * * * * *

3.

No coal-tar color in the orbital area.

That coal-tar colors are not harmless for use in preparations applied to the area of the eye, which means the area bounded by the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. The application of coal-tar colors to this area may cause serious injury and even loss of sight. No coal-tar color should be certified for use in a product to be applied to the area of the eye. A coal-tar color used in a product to be applied to this area should be considered to be from a batch that has not been certified, even though such color is from a batch that has been certified for other use.

(2) a plea by the intervenor, attacking the constitutionality of Sec. 604 of the Act of June 25, 1938 (Ch. 675, 52 Stat. 1054, T. 21, 364, U. S. C. A.) if the Court 'should hold' that the Federal Security Administrator has the right and authority to promulgate regulations prohibiting the manufacture 'of cosmetics containing coal-tar colors irrespective of the actual fact that such product is harmless when applied according to directions' as violating the 5th and 14th amendments to the Constitution of the United States; (3) a motion to dismiss the amended libels for reasons set forth at length in paragraphs (a) to (f) included, which stated in substance, are as follows: (a) The Act of Congress excludes from its provisions eyelash dyes or eyebrow dyes; (b) alternatively, should the court hold that the administrator was given such authority by the Act, the amended bills 'propose a new issue contradictory and inconsistent with the allegations of the original bill because the regulation * * * provides the certification of any "batches" containing coal tar * * *'; (c) that the refusal of the administrator 'to certify any coal tar color, harmless or otherwise, is arbitrary and capricious, and confiscatory * * *'; (d) said regulation 'contravenes paragraph (A) of Sec. 361, 21 U. S. C. C. A. in that it defines "a poisonous or deleterious substance" to be other than the definition contained in paragraph A'; (e) that said regulations 'set up a different standard of determining the use of cosmetics, particularly eyelash and eyebrow tints * * * and redefines what is a "poisonous and deleterious substance"'; and (f) that the administrator failed to give proper notice of hearing before prescribing such regulations as required by T. 21 Sec. 371 (e) U. S. C. A., and finally that intervenor had no notice of such hearing at all until the libels were filed.

"On the same day, February 19th, intervenor filed answers to both amended libels.

"Counsel for the Government, likewise on that day, filed what is styled 'a motion for judgment on the pleadings' in which it was set forth that intervenor had answered the original libel admitting 'the substantial allegations (of the libel) with exception that he denied the cosmetic contains a poisonous and deleterious substance, which may render it injurious to users under conditions prescribed on the label thereof'; that the Government then filed an amended libel, charging that the product 'was not hair dye, but an eyelash and brow dye and it contained a coal tar color that has not been listed for use as a cosmetic * * * pursuant to 21 U. S. C. A. 364, and is other than one from a batch that has been certified'; that the original answer admitted these allegations to the amended libel; and that the government filed a second amendment setting forth the rules and regulations as shown by the Federal Register 'condemning a coal tar color to be used in a product to be applied in the area of the eye', which was likewise admitted by intervenor in his answer to said amendment, and this removes any dispute as to the facts, except as to the poisonous nature of the product, which was immaterial for the purpose of said motion for judgment. Counsel for intervenor stated that if the court allowed the amendment and held that the administrator could legally refuse to certify any coal tar product for use in coloring of eyelashes and eyebrows, then there would be no question but that the government would be entitled to judgment. On the other hand if it were concluded that the administrator did not have such authority or that intervenor had not been properly notified and given a chance to be heard at a hearing upon the matter before this ruling was made, then the matter should go to trial on the merits of whether the product, when used according to directions, was dangerous and injurious to the skin and eyes.

"When this Act of June 25, 1938 was under consideration by Congress, there was considerable discussion as to whether the powers to be exercised by the administrator should be subject to review by the courts, and the lawmakers went further in the matter of judicial review of his actions than had been provided in many other instances of delegation of power to make regulations having the effect of law. These provisions for review by the courts are found in Sec. 371 T. 21 U. S. C. A. Subsection (d) of section 371 provides:

The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective * * *, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

"Subsection (e) dealing with hearing and making of regulations is as follows:

The Administrator, *on his own initiative or upon an application of any interested industry or* substantial portion thereof *stating reasonable grounds therefor,* shall hold a public hearing upon a proposal to *issue, amend,* or *repeal* any regulation contemplated by any of the following sections of this chapter: 341, 343 (j), 344 (a), 346 (a) and (b), 351 (b), 352 (d), 352 (h) 354 and 364. The Administrator shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 344 (a) may be held within a reasonable time, to be fixed by the Administrator, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Administrator shall base his order *only on substantial evidence of record* at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Administrator finds that emergency conditions exist necessitating an earlier effective date, then the Administrator shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Administrator shall specify there to meet the emergency.

"It will be noted that under subsection (e) the administrator may 'on his own initiative or upon application of any interested *industry* or *substantial portion thereof* * * * shall hold a public hearing upon a proposal to *issue, amend* or *repeal* any regulation contemplated by any of the following sections * * * 364'; that he shall give appropriate notice, etc., and that no such order shall take effect until ninety days after its issue. The dates on which the orders or regula-

tions were issued in this matter appeared in the quotation from the amended bill of the government above. But the portions so quoted, as appearing in the Federal Register of May 9, 1939, do not show how or when the notice of the hearing was given or on what date it was held. (This court does not have the 4th volume of the Federal Register, the latest number furnished it being Vol. 3, published in 1938.) However, subsection (g) provides that 'a certified copy of the transcript of the record of any proceedings under subsection (e) shall be furnished by the administrator to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal libel for condemnation, exclusion of imports, or other proceedings arising under or in respect to this chapter, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f)'. This coupled with paragraph 6 of the last mentioned subsection (f) providing: 'The remedies provided for in this section shall be in addition and not in substitution for any other remedies by law', would indicate that Congress had in mind that there might arise in condemnation proceedings issues upon which proceedings before the administrator affecting the rights of the claimant under any particular libel would be such that the courts should consider and decide them, notwithstanding the remedies for review provided in subsection (f), permitting the going direct to the Circuit Court of Appeals having jurisdiction in the locality 'where any person who may be adversely affected by such order resides * * * or has his place of business' instead of resorting to an original action in a court of first instance, such as the United States District Courts. In Security Adm. vs. Quaker Oats Co., 318 U. S. 218, on p. 227, the Supreme Court with Chief Justice Stone as its organ, in referring to the procedure provided in subsection (f), states:

> The review provisions were patterned after those by which Congress provided for the review of 'quasi judicial' orders of the Federal Trade Commission and other agencies, which we have many times had occasion to construe. Under such provisions we have repeatedly emphasized the scope that must be allowed to the discretion and informed judgment of an expert administrative body.

"It becomes necessary therefore, for this court to analyze the grounds of attack upon the regulations. This is particularly true since it has, after hearing, allowed the amended libel, which, in effect, says that claimant's product was not made in compliance with the regulations, because the administrator had ruled that any and all preparations intended for use as eyelash or brow dyes containing coal tar are dangerous and therefore refused to certify any batches as harmless. Claimant admits that the administrator has excluded the use of coal tar coloring from such dyes.

"Taking up these contentions we find that they fall into two classes, thus, (1) those in which it is claimed the administrator acted beyond or without authority under the statute; and (2) the alleged unconstitutionality based upon want of proper notice and the action of the administrator in denying the right to use coal tar in claimant's preparation, which amounts to taking of his property without due process of law. As pointed out earlier herein, those in the first class are raised principally in the motion to dismiss the amended libels, while in the plea of unconstitutionality it is substantially alleged that if the Court should hold that the Administrator, under the Act, has the right and authority to promulgate regulations prohibiting the use of cosmetics containing coal tar color irrespective of the actual fact that such product is harmless when applied according to directions, then the statute is unconstitutional and conflicts with the 5th and 14th amendments: and further, 'in the alternative', that section 371 T. 21 U. S. C. A. violates the 14th amendment in that it fails to provide 'effective notice to those who may be vitally concerned by such contemplated orders, regulations, etc.'

"I think it must be conceded that Congress, in providing for review of orders and regulations made by the administrator, in the manner and by the particular procedure and courts specified in subsection (f) of 371, must have felt that this would afford adequate remedy for determining the power, authority and correctness of the administrator's action within the statute; and that to provide stability, a reasonable limit, in the matter of time, should be fixed for those contests, which it set at ninety days. (This is not to say that the issue of sufficient notice, such as to provide due process, could not be raised also in such proceedings and reviewed in what the Supreme Court in Security Adm. vs.

Quaker Oats, supra, termed 'respondent's appeal from this order' to the Court of Appeals.)

"Besides, in the first sentence of subsection (e) of Sec. 371, the 'administrator on his own initiative or on the application of any interested industry or substantial portion thereof, *shall* hold a public hearing upon a proposal' not only '*to issue*', but to '*amend or repeal* any regulation contemplated by any' section of the act, including Section 364, of T. 21 U. S. C. A., requiring that he 'shall promulgate regulations providing for the listing of coal tar colors, which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless dilutents.' In other words, regardless of the nature of the regulation and of the fact that it might have been adopted with full compliance as to notice, hearing, review, etc., it would seem 'that any industry or substantial portion thereof', could make application 'to amend or repeal' the same. Of course, what should constitute an 'industry or substantial portion thereof' is somewhat indefinite and uncertain, but the act itself does seem to provide a means for raising these issues, first before the administrator, and then, by direct appeal to the court of appeals, thus insuring a more speedy determination than if submitted to the courts of original jurisdiction, such as the present proceeding. Hence, except as to the constitutional issues of due process under the 5th and 14th amendments, raised by the charge of insufficient provision for notice and opportunity to this claimant to be heard before adoption of the regulations quoted above from the second amended bill and the wrongful taking of his property, it does not appear to this court that there is any other remedy 'provided by law', and none has been cited or referred to by complainant, by which this court can review the action of the administrator complained of in either the motion to dismiss or otherwise, which existed prior to the enactment of subsection 371 (f), and as to which the latter would be 'in addition'.

"Before this court can determine whether the notice and hearing held were sufficient to constitute due process, it will be necessary to have before it a certified copy of the proceedings had before the administrator, as provided by subsection (e) of Sec. 371, which can be obtained by claimant for use herein, under subsection (g).

"The motion to dismiss will therefore be denied, but the matter is held open upon the issues of the constitutional questions to afford the parties an opportunity to obtain and file in this case certified copies of the proceedings had before the administrator, showing specifically the time and manner of giving notice to the claimant and others in said industry, as well as the character of the hearing."

[*Opinion delivered August 6, 1945.*]

"In the opinion handed down in these consolidated cases on March 16, 1945, it was said:

> The motion to dismiss will therefore be denied, but the matter is held open upon the issues of the constitutional questions to afford an opportunity to obtain and file in this case certified copies of the proceedings had before the administrator, showing specifically the time and manner of giving notice to the claimant and others in said industry, as well as the character of the hearing.

"This ruling was made upon motion of the claimant or intervenor to dismiss the libel, and as indicated therein, the Court considered the only serious issue to be the constitutional one as to whether a reasonable opportunity to be heard had been afforded the intervenor and others in its position before the regulation prohibiting the use of coal tar in the manufacture of eye-lash and brow tints was adopted.

"In compliance with the suggestion or requirement contained in the concluding paragraph of the opinion quoted above, counsel for the government obtained and filed in the record the following:

"(1) A press release under date of January 6, 1939, of a hearing to be had on February 6, 1939, in one of the buildings occupied by the Secretary of Agriculture in Washington, D. C., at which all persons using or proposing to use coal tar or its products in the manufacture of commodities for sale to the public, would be given an opportunity to be heard, either in person or through representative;

"(2) Three copies of the Federal Register of dates January 7, April 8 and May 9, respectively.

"(1) The press release stated that at the proposed hearing there would be considered 'some one hundred and thirty-two coal tar colors on which interested persons may submit testimony concerning harmlessness and suitability for use.' It also stated that "It is not proposed to certify any color for use in eyelash or eyebrow dyes.' Presumably this release was published in the various trade journals of the many businesses or industries using coal tar colors.

"(2) The Federal Register of January 7, 1939, among other things dealing with coal tar colors, etc., contained the following:

Notice of public hearings for the purpose of receiving evidence upon the basis of which regulations may be promulgated providing for the listing of coal-tar colors which are harmless and suitable for use in foods, drugs and cosmetics, drugs and cosmetics, and externally applied drugs and cosmetics; for the certification of batches of such colors; for procedures thereunder; and for the payment of fees therefor.

* * * * * * *

(c) The authorization contained in these regulations for the certification of coal-tar colors for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, shall not be considered to authorize the certification of any coal-tar color for use in an eyelash dye or an eyebrow dye. A coal-tar color so used shall be considered to be from a batch that has not been certified in accordance with these regulations, even though such color is from a batch that has been certified for other use.

"The issue of April 8, 1939 contained the following:

DEPARTMENT OF AGRICULTURE
FOOD AND DRUG ADMINISTRATION

In the matter of public hearing for purpose of receiving evidence upon basis of which regulations may be promulgated providing for listing of coal-tar colors which are harmless and suitable for use in foods, drugs, and cosmetics, drugs and cosmetics, and externally applied drugs and cosmetics; for certification of batches of such colors; for procedures thereunder; and for payment of fees therefor.

* * * * * * *

No direct, positive testimony was introduced by other interested persons to controvert, or tending to controvert, the testimony introduced by the Department to the effect that the application of any coal-tar color to the orbital area is liable to cause serious consequences, even resulting in impairment or loss of sight, and that no coal-tar color should be considered for listing for use in that area.

* * * * * * *

No coal-tar color in the orbital area. That coal-tar colors are not harmless for use in preparations applied to the eye. The anatomical structure of the eye includes the area bounded by the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. The application of coal-tar colors to this area may cause serious injury and even loss of sight. A coal-tar color which is certified for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, should not be certified for use in a product to be applied to the eye. A coal-tar color used in a product to be applied to the eye should be considered to be from a batch that has not been certified, even though such color is from a batch that has been certified for other use. (R., pp. 32, 33, 78, 234–37, 413, 437, 438, 498, 599, 433; Government's Exhibit No. 1)

"The issue of May 9, 1939, contained the following, among others, on the subject of use of coal tar for colors:

RULES, REGULATIONS, ORDERS

TITLE 21—FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

In the matter of public hearing for purpose of receiving evidence upon basis of which regulations may be promulgated for listing of coal-tar colors which are harmless and suitable for use in foods, drugs and cosmetics, drugs and cosmetics, and externally applied drugs and cosmetics; for certification of batches of such colors; for procedures thereunder, and for payment of fees therefor

Order of the secretary promulgating regulations effective on publication

Pursuant to, and under and by virtue of, the authority and direction of the Federal Food,

Drugs, and Cosmetic Act (Sec. 701, 52 Stat. 1055; 21 U. S. C. 371 (e); Sec. 406 (b), 52 Stat. 1049; 21 U. S. C. 346 (b); Sec. 504, 52 Stat. 1052; 21 U. S. C. 364; Sec. 706, 52 Stat. 1058; 21 U. S. C. 376, and based upon substantial evidence of record at the hearing in the above entitled matter, detailed findings of fact are made, as follows:

* * * * * * *

No coal-tar color in the orbital area. That coal-tar colors are not harmless for use in preparations applied to the area of the eye, which means the area bounded by the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. The application of coal-tar colors to this area may cause serious injury and even loss of sight. No coal-tar color should be certified for use in a product to be applied to the area of the eye. A coal-tar color used in a product to be applied to this area should be considered to be from a batch that has not been certified, even though such color is from a batch that has been certified for other use.

"From this showing it is evident that the claimant and all other interested persons were given all the notice possible, in view of the very large numbers of persons and industries involved. It further appears that all of those who filed appearances either in 'person or through representative', were given ten days in which to file briefs or arguments upon any point involved; and that such exceptions as were filed were duly considered, some sustained and others rejected. None appeared to have been made to the regulation providing that no batches of dye would be certified for use in eyelash or eyebrow tint.

"On April 19, 1945, a further hearing was had by the court in this case, at which these exhibits were filed. Subsequently, in the month of July, the exact date does not appear in the minutes, counsel for claimant brought the matter to the attention of the court, and advised that he did not intend to file further briefs, as had been suggested at the time of the hearing, and requested that the case be disposed of as it stood.

"Without finding it necessary to go further into the facts or law thus presented, it is sufficient to say that, in my opinion, there was due process and a compliance with the statute and that the plea of unconstitutionality of intervenor must fail.

"The motion to dismiss will therefore be overruled."

[*Opinion delivered August 21, 1945.*]

"The nature of this case, including pleadings and issues, was fully set forth in the opinions handed down by this court on March 17 [or 16] and August 5th [or 6th], 1945, and will not be repeated.

"It was held that the only question that could be considered was the one of compliance with the due process clause of the Federal Constitution, by the Administrator, in adopting the regulations which prevent the use of coal tar or its derivatives in the manufacture of eyelash or eyebrow coloring. It was held that, if sufficient notice and opportunity to be heard, within Constitutional requirements, had been afforded to the claimant here, and others in a similar situation, that the sole procedure for a review of the action of the Administrator is provided by the statute itself, and that is, through appeal from the ruling of the Administrator to the Circuit Court of Appeals having jurisdiction. See sub-paragraph (f) Sec. 371 T. 21 USCA.

"The bill in this case, as amended, charges that the product in question is made from coal tar or a coal tar derivative, which has not been certified for use therein in violation of the regulations adopted by the Administrator. This is admitted by defendant, but he denies that his product is dangerous when applied according to directions. In this situation I am of the opinion that the admission is sufficient to warrant granting of the injunction and that the action of the Administrator on the evidence produced at the hearing can be reviewed only through the appellate procedure provided by the Act.

"There should be summary judgment as prayed for."

On September 15, 1945, the court accordingly ordered the product condemned and destroyed. Stay of execution was subsequently ordered, and the case was appealed to the Circuit Court of Appeals for the Fifth Circuit. On March 19, 1946, the judgment of the district court was affirmed by the circuit court of appeals with the following opinions:

HOLMES, *Circuit Judge:* "These two libels *in rem* were filed by the United

States against 3 7/12 dozen packages and 26 cartons, respectively, of Nu-Charme Perfected Brow Tint. They were disposed of on the pleadings pursuant to a stipulation of the parties. These appeals were taken from judgments confiscating the property and ordering its destruction. For a statement of the facts pleaded and the issues presented, see the opinions of the court below in 59 F. Supp. 284, 61 F. Supp. 847, and 61 F. Supp. 850.

"It appears from the pleadings without contradiction that the property seized contains a poisonous and deleterious substance, namely, para-phenylene diamine, which is considered a coal-tar color since it is derived from coal-tar and imparts color when applied to other substances; but the appellant, doing business as Nu-Charme Laboratories, intervened as claimant and denied that the product might be injurious to users under the conditions of use prescribed in the labeling thereof. The sole issue upon the pleadings was and is whether the aforesaid consignments of eyebrow and eyelash dye, which had been shipped in interstate commerce for cosmetic use in the area of the eye, were adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act.[1]

"A cosmetic is deemed adulterated under said act if it is not a hair dye and bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations providing for the listing of coal-tar colors that are harmless for use in cosmetics.[2] It being undisputed that the cosmetics seized contain a coal-tar color, the appellant assails the administrator's action in banning all such colors for use in preparations applied in the orbital area.

"The promulgating authority granted to the administrator is a quasi-legislative power.[3] He is given a wide discretion and his judgment, if based on substantial evidence of record and within statutory and constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion.[4] The statute contemplates that he shall not arbitrarily exercise his power, but shall act only upon a conscientious judgment derived from a consideration of the facts and conditions to which the regulation is to be applied.[5]

"Section 371 (e) of the act authorizes the administrator to hold public hearings after appropriate notice thereof is given. Such notice was given in this instance and published in the Federal Register as provided by law.[6] It set forth the proposal in general terms, and specified the time and place for the hearing to be held, which was not less than thirty days after the date of the notice.[7] The hearing was had, findings of fact were made from evidence of record, and the regulation was duly promulgated.[8] Appellant contends that the regulation promulgated by the administrator may be collaterally attacked in condemnation proceedings, but we agree with the trial court that it is not open to collateral attack, except upon constitutional grounds, since the statute was fully complied with in every respect and provides that the procedure for review of the action of the administrator shall be by appeal to the proper circuit court of appeals.[9]

"The regulation was promulgated according to the policy set forth in the act; the method prescribed was the listing of coal-tar colors found to be harmless, and certification of batches of such colors; a standard was furnished in prescribing that the regulation would list only such colors as were found to be harmless and suitable for use. Congress stated the general rule, and left to the administrator the duty of ascertaining what particular colors should be listed.[10] This procedure meets the test required by the due-process clause of the Fifth Amendment.

"Counsel for appellant stated that if the administrator could legally refuse to certify any coal-tar product for use in coloring eyebrows and eyelashes, then there would be no question but that the Government would be entitled to

[1] 21 U. S. C. A. 361 (a) (e).
[2] 21 U. S. C. A. 361 (e) and 364.
[3] 21 U. S. C. A. 364.
[4] Security Admr. v. Quaker Oats Co., 318 U. S. 218, 228.
[5] Twin City Milk Producers Ass'n. v. McNutt, 122 F. (2) 564.
[6] 44 U. S. C. A. 308.
[7] Federal Register, Vol 4, No. 89, beginning on page 1922.
[8] 21 U. S. C. A., Sec. 371 (e).
[9] 21 U. S. C. A., Sec. 371 (f).
[10] 21 U. S. C. A., Sec. 364.

judgment. We agree with this statement and have examined the facts upon which the regulation was issued. The evidence as to the poisonous and pernicious effect liable to be caused by the application of any coal-tar color to the orbital area was not controverted by any direct and positive testimony of record. At the hearing on the proposed regulation for listing of colors suitable for use, the administrator found that coal-tar colors are not harmless for use in preparations applied in the orbital area, which includes the eyebrows, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeballs, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. He found that the application of coal-tar colors to this area may cause serious injury and even loss of sight. Thereupon, he issued the regulation that no coal-tar color should be certified for use in a product to be applied in the area of the eye. Such quasi-legislative action was not arbitrary or capricious but was the reasonable exercise of a sound judgment and discretion.

AFFIRMED."

SIBLEY, *Circuit Judge*, concurring: "I agree to the judgment, but think it a more direct and satisfactory thing to say simply that the Statute, 21 U. S. C. A., § 361 (e), positively declares that a cosmetic is adulterated if it is not a hair dye and bears or contains a coal tar color other than one from a batch that has been certified according to regulations as provided by § 364; and that this cosmetic is not a hair dye and does contain a coal tar color not from a certified batch. It cannot be sold and may be forfeited by the terms of the statute alone. If the Administrator ought under § 364 to make a list of harmless coal tar colors, and ought to include this one, some procedure must be resorted to other than to sell the cosmetic in defiance of the statute."

114. Adulteration of Nu-Charme Perfected Brow Tint. U. S. v. 14 Cartons of Nu-Charme Perfected Brow Tint. Default decree of condemnation and destruction. (F. D. C. No. 13799. Sample No. 61816–F.)

LIBEL FILED: On or about September 19, 1944, Eastern District of Texas.

ALLEGED SHIPMENT: On or about June 8, 1944, by the Nu-Charme Laboratories, Texarkana, Ark.-Tex.

PRODUCT: 14 cartons, each containing, among other items, 4 bottles of solutions labeled "Nu-Charme No. 1," "Nu-Charme No. 2," "Nu-Charme No. 4," and "Nu-Charme No. 5" and a package of a powder labeled "Nu-Charme No. 3," at Kilgore, Tex.

Examination showed that Nu-Charme No. 1 consisted essentially of 4 percent paraphenylenediamine dissolved in water; that Nu-Charme No. 2 was a solution of hydrogen peroxide; that Nu-Charme No. 3 consisted of magnesium oxide; that Nu-Charme No. 4 was a solution of boric acid; and that Nu-Charme No. 5 was light mineral oil.

LIBEL IN PART: "Nu-Charme Perfected Brow Tint Jet Black."

NATURE OF CHARGE: Adulteration, Section 601 (a), the product contained a poisonous or deleterious substance, paraphenylenediamine, which might have rendered it injurious to users under the following conditions of use prescribed in the labeling: "Use Glass, China, or Wooden Dish for Mixing Fifteen (15) drops Solution No. 1 with Fifteen (15) drops Solution No. 2; to this add enough Powder No. 3 to make thick paste. Be sure paste will not run. Application Using small clean orange stick apply dye mixture to lashes . . . then to brows. Leave mixture on until dry . . . 10 to 15 minutes. * * * Do Not Let Patron Open Eyes Until All of Mixture Has Been Removed."

DISPOSITION: October 25, 1944. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

115. Adulteration of Kix Kinks—Hair Straiter. U. S. v. Dorosy, Inc., and Dorothy Herrmann. Pleas of guilty. Each defendant fined $300. (F. D. C. No. 7741. Sample Nos. 66337–E, 71260–E, 77883–E, 87596–E, 87600–E, 92578–E.)

INFORMATION FILED: November 15, 1944, Southern District of New York, against Dorosy, Inc., New York, N. Y., and Dorothy Herrmann, president of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of April 6 and June 13, 1942, from the State of New York into the States of Illinois, Ohio, New Jersey, Maryland, and California, and the District of Columbia.

PRODUCT: Analysis of the product showed that it consisted essentially of free al-